FAQ Regarding Research Funding from FDA/CTP

Q. FDA/CTP has regulatory authority over the manufacture, marketing and distribution of tobacco products. What are some examples of these authorities?

A. The Family Smoking Prevention and Tobacco Control Act gave FDA responsibility for and authority to, among other things:

- Restrict cigarettes and smokeless tobacco retail sales to youth
- Restrict the sale and distribution tobacco products, including advertising and promotion, as appropriate to protect public health
- Review modified risk tobacco products, such as those marketed for use to reduce harm, prior to their introduction to the market
- Adjust warning labels for cigarettes and smokeless tobacco products in order to promote greater public understanding of the risks of tobacco use
- Establish standards for tobacco products (for example, setting limits on harmful and potentially harmful constituents and nicotine levels) as appropriate to protect the public health
- Review new tobacco products prior to their introduction to the market

For more information, see "Overview of the Family Smoking Prevention and Tobacco Control Act" at http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM246207.pdf

Q. In general, what areas of research are not within FDA/CTP's regulatory authority?

A. The Family Smoking Prevention and Tobacco Control Act gives FDA the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by youth. In general, CTP's regulatory authorities do NOT extend to the following:

- Setting tax rates for tobacco products
- Regulating therapeutic products, such as those marketed to treat tobacco dependence
- Setting clean indoor air polices
- Regulating tobacco growing

Q. Is a treatment intervention study designed to compare the effectiveness of a tobacco product and a treatment for tobacco dependence (medications and/or behavioral counseling) on tobacco cessation considered responsive?

A. No. CTP's regulatory authority does not extend to regulating therapeutic uses of tobacco products as this authority rests with other Centers within FDA. Examples of research projects that would be considered responsive include an observational study to examine the natural history of whether participants quit smoking cigarettes while using a different tobacco product, and assessing if communications regarding the health consequences of using tobacco products has an impact on usage rates.* In many of its key regulatory areas, CTP is

charged with assessing the impact of tobacco products on the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products as well as the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products.

Q. Is a research proposal in which the primary outcome informs treatment of disease considered responsive?

A. No. CTP does not regulate products intended for the treatment of disease. However, if the primary outcome of a research project identifies differential effects of various tobacco products on disease risk, incidence, or progression of disease, then the proposal would be considered responsive.* Examples include:

- pulmonary function testing outcomes following use of various combustible tobacco products
- oral manifestations following use of various tobacco products, especially new and emerging tobacco products

Q. What types of biomarker research may be appropriate for FDA/CTP funding?

A. Proposals identifying biomarkers of specific tobacco product exposure and/or disease and those with the potential to differentiate exposure of differing tobacco products could be considered responsive. Examples* include:

- Biomarkers to measure exposure to new and emerging tobacco products
- Biomarkers of disease (e.g., cancer, cardiovascular disease, pulmonary disease, reproductive and developmental effects) that can be associated with specific measures of tobacco exposure
- Development of a nonclinical biomarker of disease coupled to traditional toxicology and/or pharmacology studies to provide a relevant framework for the regulatory application
- Studies linking biomarkers of disease in nonclinical models that translate to biomarkers that are measurable in the clinical setting
- Magnitude of changes in biomarkers of that translates into clinically meaningful impacts on human health outcomes
- Novel biological and physiological markers (including genetic and epigenetic markers) that are predictive of smoking-related and smokeless tobacco-related adverse health outcomes

Biomarker proposal in which the primary focus is to inform treatment would not be responsive.

Q. What types of research on nicotine and/or nicotinic receptors are appropriate for consideration of funding by CTP?

A: If the research provides information on outcomes such as motor activity, memory, or neuronal responses to particular ligands, the research is likely not appropriate. Research to

rapidly screen tobacco constituents for activity at the nicotinic receptor to determine their dependence potential would be considered responsive.*

Q. What types of international research would be considered responsive?

A. In general, if study results can be generalized to the U.S. (based on the products tested and the population being sampled), it would be considered responsive. Studies evaluating toxicity, disease risk in humans would likely be responsive if a similar product is planned to be or is marketed in the U.S. Studies assessing consumer behavior and/or perceptions may or may not be responsive, since consumer behavior and perceptions may be driven by a number of factors unique to a specific country.

Q: Are studies on the impact of state and local tobacco control policies responsive?

A: The Family Smoking Prevention and Tobacco Control Act gives FDA the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by youth. Studies evaluating the impact of a tobacco tax increase are not responsive, as CTP does not have regulatory authority regarding tax rates on tobacco products. Similarly, CTP does not have authority over the sale of tobacco cessation medications, so, for example, a study evaluating the effectiveness for tobacco cessation of providing free nicotine replacement therapy would not be considered responsive. Studies evaluating the impact of a tobacco advertising restriction, a ban on the sale of flavored tobacco products, or restrictions on the sale of single serving products, however; may be considered responsive.*

Q. What will be the availability of confidential information obtained by the FDA, for example, product and constituent reporting?

A. Several laws govern the confidentiality of tobacco product information submitted to FDA, including sections 301(j) and 906(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Trade Secrets Act, and the Freedom of Information Act, as well as FDA's implementing regulations. FDA's general regulations concerning the public availability of FDA records are contained in 21 CFR Part 20. Regarding the reporting of constituents, the FD&C Act requires tobacco product manufacturers and importers to report quantities of harmful and potentially harmful constituents (HPHCs) in tobacco products or tobacco smoke by brand and sub-brand. The FD&C Act also directs the Agency to publish a list of HPHCs by brand and by quantity in each brand and sub-brand, in a format that is understandable and not misleading to a layperson.

*The examples provided above are illustrative and should not be viewed as definitive or comprehensive.